News From...

The Subcommittee on
Human Rights and Wellness
Chairman Dan Burton (R ~ IN)

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"CANADIAN PRESCRIPTION DRUG REIMPORTATION: IS THERE A SAFETY ISSUE?"

"A PRESCRIPTION DRUG THAT A PATIENT CANNOT AFFORD TO BUY IS NEITHER SAFE NOR EFFECTIVE."

Washington, D.C. – The Food and Drug Administration (FDA) estimates that more than 2 million shipments of prescription drugs will cross the border from Canada into the U.S. this year. Although the FDA's official policy allows only the personal importation of certain life-saving drugs, its practice for years has been to allow individual consumers to import up to a 90-day supply of FDA-approved drugs. However, recently the FDA seems to have changed its posture. They have initiated enforcement action against American businesses that facilitate the purchase of prescription drugs from the Canadian market, citing safety concerns as their primary motivation.

Congressman Dan Burton (R-IN-5), Chairman of the House Government Reform Subcommittee on Human Rights and Wellness, will hold a hearing entitled, ***"Canadian Prescription Drug Re-importation: Is There A Safety Issue?" The oversight hearing will be held on Thursday, June 12, 2003, in Room 2154 of the Rayburn House Office Building at 2:00 p.m.***

"Americans pay higher prices for their prescription drugs than the residents of any other country in the world," said Burton. "This is an increasingly difficult burden for our aging population to bear. Far too many Americans must choose between filling their prescriptions and buying food. No American should have to make that choice."

Mr. William K. Hubbard, FDA Associate Commissioner of Policy and Planning, appeared before the Subcommittee on April 3, 2003, where his testimony focused on phony Internet drug sites and the danger they may pose to the public. The FDA focus on Internet sites ignores the fact that many Americans already drive across the Canadian border or travel in organized bus trips to get their prescriptions filled, and the FDA offered no justification for cutting off more than a million Americans from their only affordable source of life sustaining prescription drugs.

The FDA position is further weakened by the fact that Mr. Hubbard was not able to cite a single example of harm emanating from a Canadian pharmacy, whether Internet-based or otherwise. While there is some concern about counterfeiting or misbranded products being marketed in various countries, this is not the case in Canada. The drug regulatory environment in Canada is of a similar standard to the FDA's. In the May 8, 2003, edition of the *Washington Post*, Daniele Dionne, Health Canada's Associate Director General stated*:* ***"As soon as any drug crosses the border into Canada, it has to meet***

all the regulations of our laws." She described that as a clarification, not a new policy. When interviewed by the Subcommittee staff, she said that she firmly stands by that position.

Additionally, two witnesses at the April 3rd hearing advanced common-sense suggestions for guaranteeing the safety of reimported drugs. Mr. Andy Troszok testified on behalf of the Canadian International Pharmacists Association. He described Canadian pharmacy licensing procedures that ensure a high degree of safety. Dr. Elizabeth Wennar of the United Health Alliance recommended a counterfeit-proof labeling system based on the same technology that the U.S. Treasury uses in the $20 bill.

In stark contrast, the FDA offered no constructive suggestions for guaranteeing safety to American consumers, and although invited, GlaxoSmithKline failed to appear or submit written testimony. Both Mr. Hubbard and Mr. Chris Viehbacher, President of U.S. Pharmaceuticals for GlaxoSmithKline, will appear before the Subcommittee on Thursday to testify at this hearing.

Concluded Burton, "The measure of a strong society is how it takes care of its weakest members. Congress is an arm of our society that takes that responsibility seriously. The FDA has been delegated the duty of assuring that pharmaceuticals are safe and effective, and they need to remember a simple fact: ***a prescription that a patient cannot afford to buy is neither safe nor effective***."

PANEL ONE WITNESSES:

Video Presentation by Mr. Andy Troszok, Vice President Standards
Canadian International Pharmacists Association
Calgary, Alberta, Canada

Video Presentation by Dr. Elizabeth Wennar, President and CEO
United Health Alliance
Bennington, VT

Mr. William K. Hubbard, Associate Commissioner for Policy, Planning, and Legislation
U.S. Food and Drug Administration
Washington, DC

PANEL TWO WITNESSES:

Mr. Chris Viehbacher, President, U.S. Pharmaceuticals
GlaxoSmithKline
Philadelphia, PA

Mr. David Brennan, Executive Vice President for North America
AstraZeneca Pharmaceuticals, LP
Wilmington, DE

This is a follow-up to the April 3, 2003, hearing, entitled ***"International Prescription Drug Parity: Are Americans Being Protected or Gouged?"*** For more information, or to look at previous hearing resource materials, please visit Congressman Burton's designated healthcare section on his website at http://www.house.gov/burton/healthcare.htm.

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